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Re-evaluation Decision

Chlorsulfuron

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Overview

Re-evaluation Decision

After a re-evaluation of the herbicide chlorsulfuron, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing chlorsulfuron.

An evaluation of available scientific information found that products containing chlorsulfuron do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of chlorsulfuron uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of chlorsulfuron was first presented in Proposed Re-evaluation Decision document PRVD2007-09, *Re-evaluation of Chlorsulfuron*, a consultation document.¹ This Re-evaluation Decision document² describes this stage of PMRA's regulatory process for the re-evaluation of chlorsulfuron as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-09. To comply with this decision, registrants of products containing chlorsulfuron will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Chlorsulfuron, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA is taking a regulatory decision and is requiring appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy (TSMP)).

The USEPA re-evaluated chlorsulfuron and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation section of the related Proposed Re-evaluation Decision PRVD2007-09, *Re-evaluation of Chlorsulfuron*.

What Is Chlorsulfuron?

Chlorsulfuron is a herbicide used to control weeds in wheat, barley and oat crops as well as in non-crop areas, i.e. rights-of-way, industrial sites, lumberyards, railroads, airports, storage areas, pipelines and non-pasture rough turf. Appendix II lists all products containing chlorsulfuron that are registered under the authority of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Chlorsulfuron Affect Human Health?

Chlorsulfuron is unlikely to affect your health when used according to revised label directions.

People could be exposed to chlorsulfuron through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that chlorsulfuron was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Chlorsulfuron is currently registered in Canada for use on wheat, barley and oats and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for chlorsulfuron in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Chlorsulfuron Is Introduced Into the Environment?

Chlorsulfuron is unlikely to affect non-target organisms when used according to revised label directions.

Non-target aquatic organisms and terrestrial plants could be exposed to chlorsulfuron in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of chlorsulfuron was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require aquatic and terrestrial buffer zones to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of chlorsulfuron, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional advisory label statements to reduce potential runoff into aquatic habitats
- Buffer zones and a limit of one application per season to protect sensitive aquatic and terrestrial habitats

Appendix III lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection³ regarding this decision on chlorsulfuron within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmr-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

³ As per subsection 35(1) of the *Pest Control Products Act*.

References⁴**List of Studies/Information Submitted by Registrant**

PMRA 792046	1999, Technical Grade Chlorsulfuron (DPX-W4189) Manufacturing Description and Formation of Impurities, AMR 4869-98, DACO: 2.11
PMRA 792047	2001, Chlorsulfuron (DPX-W4189) Analysis and Certification of Product Ingredients for Technical Grade Material Produced at the Shanghai Manufacturing Facility, DuPont-6583, MRID: N/S, DACO: 2.12.1,2.13
PMRA 1461776	1999, Technical Grade Chlorsulfuron (DPX-W4189) Analysis and Certification of Product Ingredients [for the Manati, Puerto Rico Plant], AMR 4727-97 Rev. 1, DACO: 2.12.1,2.13

⁴ These references are in relation to the chemistry section of PRVD2007-09. They are included in this document because the PMRA reference numbers were not yet available at the time of publication of PRVD2007-09.

Appendix I Comments and Responses

1.0 Comment on rights-of-way and the terrestrial buffer zone exemption

Rights-of-ways should be expanded to include railroad ballast, rail and hydro rights-of-way, utility easements, and roads and training grounds on military bases.

Response

The PMRA agrees that the exemption of terrestrial buffer zones to rights-of-way can include railroad ballast, rail and hydro rights-of-way, utility easements, and roads and training grounds on military bases. In addition, buffer zones were recalculated to reflect the most current practices. Revised buffer zone label amendments are listed in Appendix III. Changes to buffer zone calculations are summarized in Appendix IV.

2.0 Comment on proposed groundwater and surface water statements

An objection was raised with respect to the proposed groundwater or surface water statements. These statements suggesting that chlorsulfuron has the potential to contaminate drinking water are not appropriate and should not be required on chlorsulfuron end-use product labels based on the very low dietary risk of chlorsulfuron.

Response

The statements proposed in PRVD2007-09 with respect to the protection of aquatic habitats and irrigation or drinking water supplies are not required based on the dietary risk of chlorsulfuron (i.e. through drinking water). Expected drinking water concentrations (EDWCs) were found to be lower than the drinking water levels of concern (DWLOCs) for both short-term and chronic exposure scenarios and no further mitigation measures were required.

However, general guidance for runoff is required by the PMRA on all product labels, with some exceptions. Regardless of the attributes of the active ingredient, conditions may exist (e.g. steep slope, heavy rain) that could promote the runoff of any chemical. Runoff can occur both with compounds that are soluble in water (flowing runoff) or adsorbed to soil (soil-particle movement in runoff water). Both can enter aquatic systems in runoff and pose a risk to either free-swimming or sediment-dwelling organisms, respectively. As a result, the following statements (updated to reflect current standards) will continue to be required in the **ENVIRONMENTAL HAZARDS** section of the label:

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

In addition, the following statement is required by the PMRA for all broadcast pesticide products (agricultural or commercial) with the exception of those registered for direct application to water:

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs or wetlands), estuarine/marine habitats.

The following statement is also required by the PMRA for all pesticide products. The label amendments are listed in Appendix III.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

**Appendix II Current Canadian Registered Products Containing
Chlorsulfuron as of 20 November 2007**

Registrant	Registration Number	Guarantee (%)	Product Name	Formulation Type	Class
E.I. Dupont Canada Company	19564	98	Chlorsulfuron Technical Herbicide	Solid	Technical
E.I. Dupont Canada Company	25516	75	Chlorsulfuron 75 DF MUP	Dry flowable	Manufacturing concentrate
E.I. Dupont Canada Company	17245	75	Glean Herbicide Dry Flowable	Dry flowable	Commercial
E.I. Dupont Canada Company	21533	75	Telar Herbicide Toss- N-Go Bags	Dry flowable	Commercial

Appendix III Label Amendments for Products Containing Chlorsulfuron

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

Wear a long-sleeved shirt, long pants, shoes and socks during mixing, loading, application, clean-up and repair activities.

Do not apply this product in a way that will cause this product to contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

Do not enter or allow worker entry into treated areas for 12 hours following application and until sprays have dried.

II) The following statements must be included in the **DIRECTIONS FOR USE** section:

DO NOT apply this product more than once per growing season.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuarine/marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing

height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:		
		Freshwater Habitats of Depths:		Terrestrial Habitats**
		Less than 1 m	Greater than 1 m	
Field sprayer*	Wheat, barley and oats	1	1	15
	Non-croplands	5	3	75

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

** Buffer zones for protection of terrestrial habitats are not required for use on rights-of-way, including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

Appendix IV Revised Inputs to Buffer Zone Models for Chlorsulfuron

Ground Use Data (from Canadian labels)				
Crop	Formulation Type	Method of Application	Number of Applications	Maximum Application Rate (g a.i./ha)
Wheat, barley and oats	Dry flowable	Field sprayer	1	11.25
Lumberyards, petroleum tank farms, plant sites, railroads, storage areas	Dry flowable	Field sprayer	1	90
Rough turf areas such as roadsides, airports, industrial sites, utility and highway rights-of-way, utility substations	Dry flowable	Field sprayer	1	90

Model Input Data for Aquatic Buffer Zones (from 2005 RED)		
Half-life for aquatic buffer zones	N/A	Assumed stable
Most sensitive freshwater species	<i>Pseudokirchneriella subcapitata</i>	$\frac{1}{2} EC_{50} = 2.75 \times 10^{-5} \text{ mg a.i./L}$
Most sensitive estuarine/marine species	<i>Mysidopsis bahia</i>	$\frac{1}{2} EC_{50} = 44.5 \text{ mg a.i./L}$

Model Input Data for Terrestrial Buffer Zones (from 2005 RED)		
Half-life for terrestrial buffer zones	Soil degradation half-life	320 days
Most sensitive terrestrial plant species EC ₂₅ for vegetative vigour	Sugar beet – Vegetative vigour	0.011 g a.i./ha

